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MEMORANDUM

TO: Commissioners

FROM: Kevin R. McDonald
Chief, Certificate of Need

DATE: June 17, 2016

SUBJECT: Kaiser Permanente Baltimore Surgical Center
Docket No. 16-03-2372

Enclosed is the staff report and recommendation for a Certificate of Need ("CON") application filed by Kaiser Foundation Health Plan of The Mid-Atlantic States, Inc. ("Kaiser").

Kaiser proposes to expand its ambulatory surgery facility at the Kaiser Permanente South Baltimore County Medical Center ("Center"), which is located at 1701 Twin Springs Road in Halethorpe, to add a third operating room (OR). The surgical facilities at the Center received Certificate of Need (CON) approval in 2010, and included shelled space for a third OR in the project plan. It opened in April 2013.

The estimated cost of the project is $1,600,405 to finish the shelled space and will be paid for out of cash reserves.

Staff recommends APPROVAL of the project based on its conclusion that the proposed project complies with the applicable standards in COMAR 10.24.11, the State Health Plan for General Surgical Services Commission, and the other applicable CON review criteria at COMAR 10.24.01.08.

IN THE MATTER OF	*	**BEFORE THE**
	*	
KAISER PERMANENTE BALTIMORE SURGICAL CENTER	*	**MARYLAND HEALTH CARE COMMISSION**
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DOCKET NO. 16-03-2372	*	
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STAFF REPORT AND RECOMMENDATION

June 16, 2016

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I. INTRODUCTION

A. The Applicant

The applicant is Kaiser Foundation Health Plan of The Mid-Atlantic States, Inc. In its Mid-Atlantic States Region, "Kaiser Permanente" (a trade name) comprises Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. ("KFHP") and the Mid-Atlantic Permanente Medical Group ("MAPMG"), a multi-specialty group practice of more than 1,200 physicians with which KFHP exclusively contracts to meet the medical care needs of approximately 600,000 Kaiser Permanente members in Maryland, Virginia, and the District of Columbia. KFHP is a non-profit corporation whose sole member is Kaiser Foundation Health Plan, Inc., and was formed on or about October 9, 1980.

Kaiser Permanente (or "Kaiser") is a health maintenance organization ("HMO") with approximately 308,000 members in Maryland and owns and operates 17 outpatient medical office buildings in Maryland to provide care directly to Kaiser's members. In addition, Kaiser contracts with community practitioners and facilities to provide care that Kaiser does not provide internally or to meet the geographic access needs of its members. (DI #2, p.8)

Kaiser states that the medical centers it owns and operates focus on creating an integrated care experience to promote cost-effectiveness, efficiency, quality of care, and member convenience and satisfaction. At these centers, virtually all pharmacy, diagnostic, and laboratory services needed to support its members' needs are directly provided by Kaiser Permanente. Kaiser states that co-location of primary and specialty care with ancillary services at full-service medical centers is a key component of the Kaiser Permanente vision of comprehensive and affordable health care, allowing patients to have multiple services in the same visit and obtain better coordination of care. (DI #2, p.8)

B. The Project

The proposed project is to expand the ambulatory surgery facility at the Kaiser Permanente South Baltimore County Medical Center ("Center"), located at 1701 Twin Springs Road in Halethorpe. A third operating room (OR) is being added. The surgical facilities at the Center received Certificate of Need (CON) approval in 2010 with shelled space for a third OR included in the project plan. The facility opened in in April 2013. In addition to outpatient surgery, the Center also provides diagnostic imaging, laboratory services, therapy services, and a pharmacy. Kaiser primary and specialty care physicians are based at the center, and patients can use the center for unscheduled urgent care. (DI #2, p.9) The estimated cost of the project is $1,600,405 to finish the shelled space and will be paid for out of cash reserves.

C. Summary of Staff recommendation

Staff recommends approval of the project based on its conclusion that the proposed project complies with the applicable standards in COMAR 10.24.11, the State Health Plan for General Surgical Services. The need for the project has been demonstrated and the cost effectiveness of adding additional needed OR capacity through the finishing of space already created for this

eventuality is obvious. The project is viable and the applicant has complied with all conditions of prior CONs. The project will have a positive impact on the ability of Kaiser members to have ready access to outpatient surgery at the Center and will not have any negative impact on other health care providers.

II. PROCEDURAL HISTORY

A. Record of the Review

See Appendix A for the record of this project review.

B. Interested Parties

There are no interested parties in this review.

C. Community Support

No comments were received about the project.

D. Local Government Review and Comment

No comments on this project were provided by the local health department or any other local government body.

III. STAFF REVIEW AND ANALYSIS

The Commission considers CON applications using six criteria found at COMAR 10.24.01.08G(3). The first of these considerations is the relevant State Health Plan standards and policies.

A. The State Health Plan.

An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards, policies, and criteria.

The relevant State Health Plan for Facilities and Services ("SHP") chapter for this project review is **COMAR 10.24.11,** covering **General Surgical Services**.

COMAR 10.24.11.05 STANDARDS

A. GENERAL STANDARDS. The following general standards encompass Commission expectations for the delivery of surgical services by all health care facilities in Maryland, as defined in Health General §19-114(d). Each applicant that seeks a Certificate of Need for a project or an exemption from Certificate of Need review for a project covered by this Chapter shall address and document its compliance with each of the following general standards as part of its application

(1) Information Regarding Charges.

Information regarding charges for surgical services shall be available to the public. A hospital or an ambulatory surgical facility shall provide to the public, upon inquiry or as required by applicable regulations or law, information concerning charges for the full range of surgical services provided.

Kaiser responded that, since the vast majority of the patients served are Kaiser members,[1] there are no charges to most patients other than HMO co-payments and deductibles, as the cost of their care is covered by members' health plan premiums. Any bills for copays or deductibles come from Kaiser, and not from the Center. (DI #2, p.18)

Given the HMO model in which this facility operates and that almost exclusively serves Kaiser subscribers for which no surgical facility charge is generated, staff concludes that this standard is not applicable.

(2) Charity Care Policy.

(d) A health maintenance organization, acting as both the insurer and provider of health care services for members, if applying for a Certificate of Need for a surgical facility project, shall commit to provide charitable services to indigent patients. Charitable services may be surgical or non-surgical and may include charitable programs that subsidize health plan coverage. At a minimum, the amount of charitable services provided as a percentage of total operating expenses for the health maintenance organization will be equivalent to the average amount of charity care provided statewide by ASFs, measured as a percentage of total ASF expenses, in the most recent year reported. The applicant shall demonstrate that:

(i) Its track record in the provision of charitable health care facility services supports the credibility of its commitment; and

(ii) It has a specific plan for achieving the level of charitable care provision to which it is committed.

(iii) If the health maintenance organization's track record is not consistent with the expected level for the population in the proposed service area, the applicant shall demonstrate that the historic level of charity care was appropriate to the needs of the population in the proposed service area.

Section (d) of this standard is the section that applies to this application by Kaiser, an HMO. Kaiser stated that it provides charitable care and coverage as part of its non-profit mission to improve health in the communities it serves. In this case, rather than providing a set amount of charity care for surgical services, it provides financial assistance to reduce barriers to care and health coverage. Kaiser states that it works with community organizations and local governments to enroll uninsured low income individuals and families that have no access to any other public or private care and coverage available to them. Thus individuals receiving charitable care from a

[1] There were no non-Kaiser subscribers treated at the ASC in 2013-15. (DI#9, completeness responses)

Kaiser ambulatory surgical facility ("ASF") would primarily be existing participants in one of Kaiser's charitable health programs, or members needing assistance with co-payments and cost shares, rather than non-members applying for financial assistance with surgical procedure costs. (DI #2, p..21)

In 2014, Kaiser's provision of charitable health care was 0.6% of total operating expenses, exceeding the statewide ASF average of 0.46%.[2] Kaiser's description of three of its charitable health programs follow immediately below.

Charitable Health Access Program (CHAP)	
Description	Kaiser Permanente (KP) collaborates with local governments and community based not-for-profit organizations to provide health care and coverage for uninsured families in need. CHAP helps those who do not qualify for any public or private care and coverage plans, either commercially or through the ACA, and have incomes below 300% of the federal poverty line (FPL). CHAP members receive a 100% subsidized premium and a Medical Financial Assistance Award to help reduce the copays and cost-shares of the off-exchange Gold Medal Plan. The program offers up to 24 months of comprehensive coverage to qualified families. Once enrolled, members have access to primary, specialty, and preventive care, in-patient care, health education classes and all services provided within the KP integrated delivery system. After 24 months, recertification may be an option to remain in the program. In Maryland, KP enrolls members through community partners in Anne Arundel County, Baltimore City, Baltimore County, Frederick County, Howard County, Montgomery County and Prince George's County. In 2014, Kaiser invested $10,942,434 in CHAP.
Medical Care for Children Partnership (MCCP) Programs	
Description	Kaiser Permanente partners with local governments, hospitals and/or nonprofit community groups to identify uninsured children who are ineligible for public or private health care programs and are below 300% of the FPL. Once enrolled in the program, children receive free primary care and all services available within the KP integrated delivery system. Over 3,700 children in the Mid-Atlantic Region were able to rely upon Kaiser Permanente as their medical home in 2015. In 2014, Kaiser spent $4,937,943 in charitable care expenditures for this program in Maryland. Kaiser currently participates in partnerships in Montgomery County and Prince George's County in Maryland.

[2] Kaiser reported that the total operating expenses for Kaiser Permanente Mid-Atlantic Region were $2,627,612,000; two of Kaiser's charitable programs (CHAP and MCCP) totaled $15,880,377 in 2014.

Medical Financial Assistance (MFA) Program	
Description	The Medical Financial Assistance Program is an income eligibility based financial assistance program to provide a defined amount of financial assistance to be used for health care services within Kaiser medical offices. Patients who cannot afford out-of-pocket costs of health care services may apply to this financial assistance program for free or reduced medical care services at Kaiser clinics, based on financial eligibility criteria. The MFA Program is open to Kaiser members who need assistance with co-payments for services, as well as to non-members seeking care from Kaiser medical offices. Kaiser posts information about its MFA Program on its website, kp.org, and the application for MFA appears on Kaiser's website. In addition, Kaiser displays posters and brochures in its medical offices regarding the availability of the MFA Program. Determinations of probable eligibility are made within two business days.

(DI#2, p. 21,22)

The applicant complies with the HMO requirements of the Charity Care standard.

Standards .05A(3), Quality of Care; .05A(4), Transfer Agreements; .05B(4), Design Requirements; and .05B(5), Support Services.

Among the remaining applicable standards are several that prescribe policies, facility features, and staffing and/or service requirements that an applicant must meet, or agree to meet prior to first use. Staff has reviewed the CON application and confirmed that the applicant provided information and affirmations that demonstrate full compliance with these standards:

.05A(3), Quality of Care;
.05A(4), Transfer Agreements;
.05B(4), Design Requirements; and
.05B(5), Support Services.

The applicant is in compliance with the conditions of participation of the Medicare/Medicaid program and is accredited by the Accreditation Association for Ambulatory Health Care. It has a written transfer agreement with St. Agnes Hospital. The facility is designed in compliance with Section 3.7 of the 2014 Facilities Guideline Institute Guidelines. Finally, the required support services (laboratory, radiology, and pathology) are provided by Kaiser. The text of these standards and the locations within the application where compliance is documented are attached as Appendix B.

(3), Quality of Care. See Appendix B.

(4), Transfer Agreements. See Appendix B.

B. PROJECT REVIEW STANDARDS. The standards in this section govern reviews of Certificate of Need applications and requests for exemption from Certificate of Need review involving surgical facilities and services. An applicant for a Certificate of Need or an exemption from Certificate of Need shall demonstrate consistency with all applicable review standards.

(1) An applicant proposing to establish a new hospital providing surgical services or a new ambulatory surgical facility shall identify its projected service area. An applicant proposing to expand the number of operating rooms at an existing hospital or ambulatory surgical facility shall document its existing service area, based on the origin of patients served.

Kaiser stated that it generally defines the service area for its larger specialty care centers as that area within a 30-mile radius of the facility, sometimes adjusted for the existence or lack of other Kaiser facilities in the area. Kaiser considers this facility's service area to include Baltimore City. and Anne Arundel, Baltimore, Carroll, Harford, and Howard Counties, and provided a comprehensive list of the included zip codes. (DI #2, p.25, and DI,#9)

The applicant meets this standard.

(2) Need – Minimum Utilization for Establishment of a New or Replacement Facility.

This standard is not applicable as this proposed project seeks to expand an existing facility.

(3) Need – Minimum Utilization for Expansion of an Existing Facility.

An applicant proposing to expand the number of operating rooms at an existing hospital or ambulatory surgical facility shall:

(a) Demonstrate the need for each proposed additional operating room, utilizing the operating room capacity assumptions and other guidance included at Regulation .06 of the Chapter;

(b) Demonstrate that its existing operating rooms were utilized at optimal capacity in the most recent 12-month period for which data has been reported to the Health Services Cost Review Commission or to the Maryland Health Care Commission; and

(c) Provide a needs assessment demonstrating that each proposed operating room is likely to be utilized at optimal capacity or higher levels within three years of the completion of the additional operating room capacity. The needs assessment shall include the following:

(i) Historic trends in the use of surgical facilities at the existing facility;

(ii) Operating room time required for surgical cases historically provided at the facility by surgical specialty or operating room capacity; and

(iii) Projected cases to be performed in each proposed additional operating room.

Kaiser presented the surgical volume and room utilization statistics shown in Table III-1, below. These numbers show that case volume supported a need for three ORs in 2015, and that the Center accommodated this case volume in its two ORs by operating longer hours than it – and the State Health Plan's guidance -- identify as optimal. The applicant further states that, in the longer term, it sees a need for more than one additional OR at this site but this project is going forward now to add capacity as quickly as possible, given the high recent level of capacity use.

The projections shown in Table III-1 are based on projections of growth in the number of Kaiser Baltimore Region subscribers. Table III-2 shows the relationship between Kaiser subscribers and surgical cases. As can be seen, Kaiser projects growth in surgical case volume at the Center site over the next three years lagging just behind growth in the subscriber base, the result of its assumption that the subscriber base use rate of ambulatory surgery will be trending down at a moderate pace.

Table III-1: Historical and Projected Utilization at SBCMC, 2013-2018

Calendar Year	Cases	Operating Room and OR Cleaning/Prep. Minutes			ORs Needed [3]
		Surgical procedure time	Turnover Time	Total Time	
2013 *	1,637	120,240	40,925	161,165	1.65
2014	2,237	155,674	55,925	211,599	2.16
2015	2,360	233,034	59,000	292,034	2.98
2016 projected	*2,791*	*275,533*	*69,775*	*345,308*	*3.53*
2017 projected	*3,092*	*305,250*	*77,300*	*382,550*	*3.91*
2018 projected	*3,640*	*359,373*	*91,000*	*450,373*	*4.60*

*2013 statistics are for nine months of operation Source: DI #1, p.28

[3] COMAR 10.24.11.06A identifies 1,632 hours per year (97,920 mins.) as optimal capacity for a dedicated outpatient operating room.

Table III-2: Actual and Projected Surgical Cases
KP Baltimore Region Subscribers,
2013-2018

Calendar Year	Subscribers	Year to Year Change	Cases	Year to Year Change	Cases per 100 subscribers
2013 actual *	59,780	-- --	1,637	-- --	3.64[4]
2014 actual	67,583	13.0%	2,237	2.7%[5]	3.31
2015 actual	85,183	26.0%	2,360	5.5%	2.77
2016 projected	*103,183*	*21.1%*	*2,791*	*18.3%*	*2.70*
2017 projected	*117,233*	*13.6%*	*3,092*	*10.8%*	*2.64*
2018 projected	*139,083*	*18.6%*	*3,640*	*17.7%*	*2.62*

*2013 statistics are for nine months of operation Source: DI #1, p.28, and DI,#14

Note that, for purposes of this review, these projections are not the primary consideration, given that Kaiser's actual results in 2015, at the State Health Plan optimum capacity use assumptions, hit the three OR mark. Without any appreciable increase in demand for surgery at this center, the project would still be consistent with this standard.

(4) Design Requirements. See Appendix B.

(5) Support Services. See Appendix B.

(6) Patient Safety.

The design of surgical facilities or changes to existing surgical facilities shall include features that enhance and improve patient safety. An applicant shall:

(a) Document the manner in which the planning of the project took patient safety into account; and

(b) Provide an analysis of patient safety features included in the design of proposed new, replacement, or renovated surgical facilities.

Kaiser stated that user input is being actively included in the design process through review of plans and input on equipment and design features of the ORs. Kaiser listed several factors that it believes will allow expansion of OR capacity to improve the safety of its operations. They include:

- An additional OR will allow the Center to minimize the number of procedures performed in the late afternoons and evenings, times of day when Kaiser states that industry studies have documented a higher incidence of medical errors;

[4] Use rate is based on annualizing the 1,637 cases that occurred in 9 months of operation in 2013
[5] Percentage change calculated on an annualization of the 1,637 actual cases done in nine months of 2013 . Annualized cases = 2,177.

- The new OR will be designed and equipped to closely match the two existing ORs, standardization that will allow staff to move from one room to another with minimal chance of confusion;

- Patient safety features are already incorporated in the design guidelines of the Facilities Guidelines Institute Guidelines for Design and Construction of Healthcare Facilities, which Kaiser will follow in this project. Adherence to these guidelines, specified in the State Health Plan (see .05B(4) above) primarily addresses circulation patterns in the facility, space requirements, room finishes, and air handling and filtration systems for maintenance of a sterile operating environment and the air quality levels needed to minimize surgical-related infection risk; and

- Specific consideration is being given by Kaiser to the lighting in each room to identify any opportunities to minimize staff and surgeon fatigue from that source while still maintaining the illumination levels necessary to conduct the procedures.

Kaiser also cited its investment in electronic healthcare records ("EHR") to support the delivery of care to its members and to enhance communications among its medical professionals. The system includes physician order entry for laboratory and radiology tests, as well as electronic prescribing capability connected with Kaiser pharmacy systems. The EHR allows physicians to send test orders and receive test results electronically, leading to rapid availability of test results to all Kaiser treating physicians with EHR access, prevention of duplicate testing and enhancement of patient safety. The EHR system performs other patient-safety functions as well, such as automated clinical decision support for adverse drug event prevention, drug-allergy checking, alerts when preventive health screenings are due, and medication adherence monitoring. Kaiser states that this system has increased efficiency, reduced errors, and improved patient care and patient safety.

The project complies with this standard.

(7) Construction Costs.

The cost of constructing surgical facilities shall be reasonable and consistent with current industry cost experience.

(a) Hospital projects.

Subpart (a) does not apply because this is not a hospital project.

(b) Ambulatory Surgical Facilities.

(i) The projected cost per square foot of an ambulatory surgical facility construction or renovation project shall be compared to the benchmark cost of good quality Class A construction given in the Marshall Valuation Service® guide, updated using Marshall Valuation Service® update multipliers, and adjusted as shown in the Marshall Valuation Service® guide as necessary for site terrain, number of building levels, geographic locality, and other listed factors.

(ii) If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost by 15% or more, then the applicant's project shall not be approved unless the applicant demonstrates the reasonableness of the construction costs. Additional independent construction cost estimates or information on the actual cost of recently constructed surgical facilities similar to the proposed facility may be provided to support an applicant's analysis of the reasonableness of the construction costs.

This standard requires a comparison of the project's estimated construction cost with an index cost derived from the Marshall Valuation Service ("MVS") guide. For comparison, an MVS benchmark cost is typically developed for new construction based on the relevant construction characteristics of the proposed project. The MVS cost data includes the base cost per square foot for new construction by type and quality of construction for a wide variety of building uses including outpatient surgical centers. The MVS guide also includes a variety of adjustment factors, including adjustments of the base costs to the costs for the latest month, the locality of the construction project, as well as factors for the number of building stories, the height per story, the shape of the building (such as the relationship of floor area to perimeter), and departmental use of space. The MVS Guide identifies costs that should not be included in the MVS calculations. These exclusions include costs for buying or assembling land, making improvements to the land, costs related to land planning, discounts or bonuses paid for through financing, yard improvements, costs for off-site work, furnishings and fixtures, marketing costs, and funds set aside for general contingency reserves.[6]

Kaiser is only finishing 491 square feet of existing building space, designed for this specific capacity expansion objective. Kaiser compared its estimated project costs to a benchmark cost calculated by taking the MVS base cost as of November 2015 for Class A-B, good quality outpatient surgical center construction and adjusting it for the shape of the OR, the ceiling height, and the location, updated to the month of CON application preparation. Kaiser further adjusted this benchmark cost to account for the fact that the proposed project only involves finishing space, not the construction of a completely new outpatient surgical facility. The result was a benchmark cost per square foot that is more than 15% above the project cost per square foot.

Commission staff notes that, while this project only involves the finishing of shell space, the space to be finished is for an operating room, the most expensive space within an outpatient surgery center. Therefore, Commission staff applied the MVS differential cost factor for a hospital operating rooms (1.89)[7] to the MVS base cost for Class A-B, good quality outpatient surgical centers. Commission staff applied further adjustments similar to those used by Kaiser for the shape of the OR, the ceiling height, and the location (all updated to May 2016) to derive an initial benchmark square foot cost for operating rooms of $1,027 per square foot ("SF"). To account for the fact that the project is limited to the finishing of shell space, staff calculated the cost of the shell space by applying the hospital differential cost factor for unassigned space to the adjusted base cost for an outpatient surgical center and subtracted the

[6] Marshall Valuation Service Guidelines, Section 1, p. 3 (January 2016).
[7] MVS does not include departmental differential cost factors for outpatient surgical centers

results ($271.69 per SF) from the initial benchmark to arrive at an adjusted benchmark for this project of $755.29 per square foot.

Table III-3 (below) compares Kaiser's estimated cost for finishing the space for the operating room ($403,456, or $821.70 per SF) to the MVS benchmark calculated by Commission staff ($755.29 per SF). Kaiser's cost exceeds the benchmark cost by 8.8%.

Table III-3: Comparison of SBCMC's Construction Budget to Marshall Valuation Service Benchmark

Project Construction Costs	**Construction**
Building	$366,006
Fixed Equipment	Incl. Above
Site Work	$0
Architect/Engineering Fees	$27,450
Permits	$10,000
Capital Construction Interest	$0
Total Construction Costs	$403,456
Square Feet ("SF")	491
Cost Per SF	**$821.70**
Benchmark (Adj. MVS Cost/SF for finishing the space)	**$755.29**
Over(Under)	**$66.21**
Percent Over Benchmark	**8.8%**

Source: Kaiser CON Application, page 34 and Marshall Valuation Service

The standard requires that an applicant surgery center whose projected cost per square foot exceeds the MVS benchmark cost for good quality Class A construction by 15% or more demonstrate that the construction cost is reasonable. Because the project's construction cost does not exceed the MVS benchmark by more than 15%, no such demonstration is required.

Therefore, the project is in compliance with this standard.

(8) Financial Feasibility.

A surgical facility project shall be financially feasible. Financial projections filed as part of an application that includes the establishment or expansion of surgical facilities and services shall be accompanied by a statement containing each assumption used to develop the projections.

(a) An applicant shall document that:

(i) Utilization projections are consistent with observed historic trends in use of the applicable service(s) by the likely service area population of the facility;

With regard to subpart (a)(i), the applicant submitted utilization projections that are consistent with use rate estimates based on a defined subscriber population and demonstrated how that population is projected to change. Staff notes that the Center's case volume in 2015 supports the need for a third OR.

(ii) Revenue estimates are consistent with utilization projections and are based on current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision, as experienced by the applicant facility or, if a new facility, the recent experience of similar facilities;

The Center will not charge patients for the services they obtain at the facility. As a facility operated by a staff model HMO, payments for subscriber services are covered by subscriber premiums, not fees paid for specific services. Similarly, any copayments and deductibles are charged by and accrued to Kaiser Foundation Health Plan of the Mid-Atlantic States (not to the Center). (DI #2, p.35)

(iii) Staffing and overall expense projections are consistent with utilization projections and are based on current expenditure levels and reasonably anticipated future staffing levels as experienced by the applicant facility, or, if a new facility, the recent experience of similar facilities; and

Direct care staffing is projected to increase by 2.5 FTEs (6.7%) and expenses are projected to grow by $196,000 (6.4%) in the first year of the facility's operation with three ORs. Case volume is projected to increase18%.

(iv) The facility will generate excess revenues over total expenses (including debt service expenses and plant and equipment depreciation), if utilization forecasts are achieved for the specific services affected by the project within five years of initiating operations.

The applicant stated that the expenses at the Center are entirely subsidized by Kaiser Foundation Health Plan of the Mid-Atlantic States. As noted in (ii), above, revenue accrues at that level as well.

(b) A project that does not generate excess revenues over total expenses even if utilization forecasts are achieved for the services affected by the project may be approved upon demonstration that overall facility financial performance will be positive and that the services will benefit the facility's primary service area population.

See responses to (8)(a)(ii) and (iv), immediately above.

The applicant has demonstrated the project's financial feasibility.

(9) Preference in Comparative Reviews.

In the case of a comparative review of CON applications to establish an ambulatory surgical facility or provide surgical services, preference will be given to a project that commits to serve a larger proportion of charity care and Medicaid patients. Applicants' commitment to provide charity care will be evaluated based on their past record of providing such care and their proposed outreach strategies for meeting their projected levels of charity care.

This standard is not applicable.

B. Need

COMAR 10.24.01.08G(3)(b) The Commission shall consider the applicable need analysis in the State Health Plan. If no State Health Plan need analysis is applicable, the Commission shall consider whether the applicant has demonstrated unmet needs of the population to be served, and established that the proposed project meets those needs.

This criterion directs the Commission to consider the "applicable need analysis in the State Health Plan," which, in this instance, is found in the Surgical Services Chapter at10.24.11.05B, Need – Minimum Utilization for Expansion of an Existing Facility. As previously outlined, the project is consistent with the Chapter's need standard for OR additions.

C. Availability of More Cost-Effective Alternatives

The Commission shall compare the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities, or through an alternative facility that has submitted a competitive application as part of a comparative review.

The option of adding more than one OR was considered, but without existing space to house this additional surgical capacity, this option would require relocating adjacent services, causing "a domino effect of renovation and relocation" and a longer time frame for project implementation. The simpler option chosen by Kaiser was to fit out the shelled space already in place for expansion in order to handle current levels of demand for OR time. (DI#2, p.43)

While a larger and more time-consuming expansion option may have proven to be more effective relative to its cost in the longer term, the option chosen by Kaiser is reasonable, The first expansion option already designed into the facility will quickly address Kaiser's current need for more OR capacity.

D. Viability

The Commission shall consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project within the time frames set forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project.

The applicant submitted audited financial statements for Kaiser Foundation Health Plan of the Mid-Atlantic States that demonstrate that Kaiser has adequate funds for this modest project. (DI #2) However, the financial statements also showed a cumulative loss of over $31 million for 2013 and 2014. Asked to address this performance, Kaiser submitted a projected profit and loss statement for Kaiser Permanente Mid-Atlantic States (KPMAS) operations for the next ten years which was based on the KPMAS long-term strategic plan. This projection shows that the organization anticipates reversing the losses from 2013/2014.. KPMAS projects an ability to increase revenue through membership growth while reducing its rate of expense growth over time. Kaiser stated that KPMAS has seen a significant increase in membership, in line with the planned financial turnaround.

Staff recommends that the Commission find this project to be viable.

E. Compliance with Conditions of Previous Certificates of Need

An applicant shall demonstrate compliance with all terms and conditions of each previous Certificate of Need granted to the applicant, and with all commitments made that earned preferences in obtaining each previous Certificate of Need, or provide the Commission with a written notice and explanation as to why the conditions or commitments were not met.

The applicant stated that Kaiser received three CONs in 2010 to establish three separate ambulatory surgical facilities in Largo (Docket No. 09-16-2304), Gaithersburg (Docket No. 09-15-2303), and Baltimore (Docket No. 10-03-2306). Each of these projects was approved with the condition that it:

- Provide the Commission with documentation of obtaining accreditation from the Joint Commission on Accreditation of Healthcare Organizations or the Accreditation Association for Ambulatory Health Care within 18 months of first use approval; and,
- Execute a transfer agreement that meets the requirements of the Department of Health and Mental Hygiene regulations implementing Health-General Article, §19-308.2, Annotated Code of Maryland.

Kaiser met both conditions for all three projects, which timely received First Use Approval from MHCC staff. The applicant has demonstrated compliance with all terms and conditions of previous CONs.

F. Impact on Existing Providers

An applicant shall provide information and analysis with respect to the impact of the proposed project on existing health care providers in the health planning region, including the impact on geographic and demographic access to services, on occupancy, on costs and charges of other providers, and on costs to the health care delivery system.

Kaiser responded that this project does not have an impact on other facilities, as it is intended to improve the ability of the Center to handle the case volume it is already experiencing. Similarly, it will have no impact on payer mix, as it is used nearly exclusively by Kaiser Permanente subscribers, who will have better availability and access to surgical care as a result of this project. Kaiser also states that it will have no impact on costs to the health care system, as it has no impact on Kaiser Permanente premiums and is intended to serve subscribers already using the Center.

Staff concludes that the impact of this project is positive for Kaiser members and that there will be no negative impact on existing providers.

IV. SUMMARY AND STAFF RECOMMENDATION

Based on its review of the proposed project's compliance with the Certificate of Need review criteria in COMAR 10.24.01.08G(3)(a)-(f) and the applicable standards in COMAR 10.24.11, the General Surgical Services Chapter of the State Health Plan, Commission staff recommends that the Commission find that the proposed capital project complies with the applicable State Health Plan standards, is needed, is a cost-effective approach to meeting Kaiser's objectives, is viable, is proposed by an applicant that has complied with the terms and conditions of previously issued CONs, and will have a positive impact on Kaiser's ability to provide outpatient surgery to its members without adversely affecting costs and charges or other providers of surgical care.

Accordingly, Staff recommends that the Commission **APPROVE** the application of the Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. for a Certificate of Need authorizing the addition of a third operating room through the finishing of existing space at its South Baltimore County Medical Center .

IN THE MATTER OF	*	**BEFORE THE**
	*	
KAISER PERMANENTE BALTIMORE SURGICAL CENTER	*	**MARYLAND HEALTH CARE COMMISSION**
	*	
DOCKET NO. 16-03-2372	*	
	*	

*** ***

FINAL ORDER

Based on the analysis and conclusions in the Staff Report and Recommendation, it is this 16th day of June, 2016, by the Maryland Health Care Commission, **ORDERED:**

That the application by Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. for a Certificate of Need to add an operating room through the finishing of existing shelled space at the Kaiser Permanente South Baltimore County Medical Center at a cost of $1,600,405 be, and hereby is, **APPROVED**.

MARYLAND HEALTH CARE COMMISSION

June 16, 2016

Appendix A: Record of the Review

APPENDIX A: Record of the Review

Docket Item #	Description	Date
1	Ruby Potter acknowledges receipt of Letter of Intent to file CON application.	12/9/15
2	Certificate of Need Application filed.	2/5/16
3	Ruby Potter acknowledges receipt of application for completeness review.	2/8/16
4	Ruby Potter sends request to publish notice of receipt of application to the Baltimore Sun.	2/8/16
5	Request to publish notice of receipt of application sent to Maryland Register.	2/8/16
6	Notification published in the Baltimore Sun.	3/2/16
7	MHCC staff sends letter requesting completeness information.	3/2/16
8	E-Mails between consultant Solberg and MHCC's McDonald requesting and granting extension to file completeness by 3/30/16.	3/8/16
9	Response to completeness letter received.	4/4/16
10	Request sent to Maryland Register to publish notice of formal start of review.	4/29/16
11	Ruby Potter notifies applicant that formal start of review will be 5/13/16	5/2/16
12	Potter to Baltimore Sun – Request to publish notice of formal start of the review will be 5/13.	5/2/16
13	Form sent requesting comments from local health department.	5/2/16
14	Email exchange between Kevin McDonald and Kaiser's Adam Pender to add 2013 data to complete Table III-2 of this report.	6/6/16

APPENDIX B

Excerpted CON standards for General Surgical Services From State Health Plan Chapter 10.24.11

Excerpted CON standards for General Surgical Services
From State Health Plan Chapter 10.24.11

Each of these standards prescribes policies, services, staffing, or facility features necessary for CON approval that MHCC staff have determined the applicant has met. Bolding added for emphasis. Also included are references to where in the application or completeness correspondence the documentation can be found.

STANDARD	**APPLICATION REFERENCE (Docket Item #)**
A. (3) Quality of Care. A facility providing surgical services shall provide high quality care. … (c) An existing ambulatory surgical facility shall document that it is: (i) In compliance with the conditions of participation of the Medicare and Medicaid programs; and (ii) Accredited by the Joint Commission, the Accreditation Association for Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgery Facilities, or another accreditation agency recognized by the Centers for Medicare and Medicaid as acceptable for obtaining Medicare certification. (d) A person proposing the development of an ambulatory surgical facility shall demonstrate that the proposed facility will: (i) Meet or exceed the minimum requirements for licensure in Maryland in the areas of administration, personnel, surgical services provision, anesthesia services provision, emergency services, hospitalization, pharmaceutical services, laboratory and radiologic services, medical records, and physical environment. (ii) Obtain accreditation by the Joint Commission, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities within two years of initiating service at the facility or voluntarily suspend operation of the facility.	DI#2, p.23
A.(4) Transfer Agreements. (a) Each ASF and hospital **shall have written transfer and referral agreements** with hospitals capable of managing cases that exceed the capabilities of the ASF or hospital.	DI #2, p. 24

(b) Written transfer agreements between hospitals shall comply with the Department of Health and Mental Hygiene regulations implementing the requirements of Health-General Article §19-308.2.	
B. (4) <u>Design Requirements</u>. Floor plans submitted by an applicant **must be consistent with the current FGI Guidelines.** (a) A hospital shall meet the requirements in Section 2.2 of the FGI Guidelines. (c) Design features of a hospital or ASF that are at variance with the current FGI Guidelines shall be justified. The Commission may consider the opinion of staff at the Facility Guidelines Institute, which publishes the FGI Guidelines, to help determine whether the proposed variance is acceptable.	DI #2, p. 29 and DI# 9, p.4 and Exhibit 4
B.(5) <u>Support Services</u>. Each applicant **shall agree to provide as needed, either directly or through contractual agreements, laboratory, radiology, and pathology services**.	DI #2, p. 29